

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/442,111 11/17/99 DEFREES

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TOWNSEND AND TOWNSEND AND CREW  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO CA 94111-3834

EXAMINER

| FRONDA, C |              |
|-----------|--------------|
| ART UNIT  | PAPER NUMBER |

1652  
DATE MAILED:

08/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

|                              |  |                                       |
|------------------------------|--|---------------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/442,111</b>   | Applicant(s)<br><b>Defrees et al.</b> |
|                              | Examiner<br><b>Christian L. Fronda</b> | Art Unit<br><b>1652</b>               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above, claim(s) 1-52 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 53-71 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a)  All b)  Some\* c)  None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
- 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Claims 53-71 in Paper No. 10 (**RESPONSE** dated May 15, 2001) is acknowledged. The traversal is on the ground(s) that the product claims and process claims are not related as a product and process of making and that the particular glycosyltransferases and nucleotide sugars do not require separate searches.

This is not found persuasive because the process claims use the products contained in the reaction mixtures which comprise an acceptor saccharide and plant or microorganism cell that produces a nucleotide sugar and a recombinant glycosyltransferase. Furthermore, the processes for using the products as claimed can be practiced with other materially different products such as using chemical reagents and catalysts in a chemical synthesis of a saccharide. Each of the claims of the inventions of Groups I-V are directed toward patentably distinct species of glycosyltransferases. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 53-71 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 53-59, 61, and 66-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any the use of any "enzymatic system for forming a nucleotide sugar" or any fusion protein consisting of an "enzyme for forming a nucleotide sugar and the glycosyltransferase". The specification, however, only provides the following representative species of sugar nucleotide regeneration cycles encompassed by the claims: GlcNAc Cycle, Gal

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Cycle-1, Gal Cycle-2, ST Cycle, Fuc Cycle-1, GalNac Cycle-1, GalNAc-Cycle 2, Man Cycle, and Fuc Cycle-2 (see Specification, Table 1, p. 28). Furthermore, the specification provides the following representative species of fusion protein encompassed by the claims: CMP-sialic acid synthase/α2,3 sialyltransferase fusion protein (see Specification, pp. 60-64).

There is no written description of any other “enzymatic system for forming a nucleotide sugar” or any other fusion protein consisting of an “enzyme for forming a nucleotide sugar and the glycosyltransferase” other than the sugar nucleotide regeneration cycles or the CMP-sialic acid synthase/α2,3 sialyltransferase fusion protein stated above. The specification also fails to describe additional representative species of any other “enzymatic system for forming a nucleotide sugar” or any other fusion protein consisting of an “enzyme for forming a nucleotide sugar and the glycosyltransferase” by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 54-59, 61, and 66-71 which depend from claim 53 are also rejected because they do not correct the defect of claim 53.

***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 53-71 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.  
The omitted steps are: isolating and recovering the produced product saccharide. Claims 52-71 which depend from claim 53 are also rejected because they do not correct the defect of claim 53.
7. Claims 53-59, 61, and 65-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
In claim 53, the phrase “enzymatic system for forming a nucleotide sugar” renders the claim indefinite because the specific enzymes comprised by the “enzymatic system” and the specific “nucleotide sugar” are not known and not defined by the specification. Claims 52-59, 61, and 65-71

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In claim 59, the phrase ““wherein the enzymatic system for forming a nucleotide sugar comprises an enzyme” renders the claim indefinite because the specific “enzyme” is not known and not recited in the claim.

***Claim Rejections - 35 U.S.C. § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 53, 54, 56-62, 66, 69, and 71 are rejected under 35 U.S.C. 102(a) as being anticipated by Gilbert et al..

Gilbert et al. teach a fusion protein that has both CMP-Neu5Ac synthetase and alpha-2,3-sialytransferase activities, wherein said fusion protein is made by expressing genes cloned from *Neisseria meningitidis* in *E. coli*, and use of said fusion protein to make sialylated oligosaccharides by contacting said fusion protein with an acceptor saccharide (see entire publication and Table 1). Thus, the reference teachings anticipate the claims.

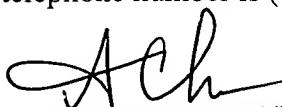
***Conclusion***

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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